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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,346	01/27/2006	Michael Cornelis Van Beek	PHNL030900US	3480

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BRIARCLIFF MANOR, NY 10510

EXAMINER

MARJAN, FARDANESH

ART UNIT	PAPER NUMBER
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3777

NOTIFICATION DATE	DELIVERY MODE
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03/18/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/566,346	Applicant(s) VAN BEEK ET AL.	
	Examiner MARJAN FARDANESH	Art Unit 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/27/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: page 7, line 9, -change "115" to "215", page 7 lines 32-33, Change "212" to "112".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16,18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 9, 10, applicant claims range within a range. By reciting three different limitations, it is unclear which range applicant intends to cover.

With respect to claims 1-10, 14-16, 18 since the phrase "whereby" implies an inherent result. It is suggested that applicant amend the claim language to read "wherein" instead of "whereby" so that the phrase following the term will be given more patentable weight.

With respect to claims 1-15, the apparatus claims drawn to apparatus, however no positively claim structures are set forth.

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With respect to claim 16, applicant should amend the language of the preamble of the claim to read “Computer executable program stored on digital storage medium wherein the program when implemented by processor performs steps of:”.

4. With respect to claim 17, the claim contains multiple recitations such as optical detection, optical spectroscopic and optical. Applicant appears to have labeled each of the means plus function elements with a preceding term; a term preceding the means plus function recitation may be interpreted to be adding additional structural limitations, per *Baran v. Medical Device Technologies*:

<http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1058.pdf>. It raises the question of whether the applicant intends to invoke 112, 6th paragraph for defining the claim elements. Therefore, it is suggested that terms proceeding the means plus function limitations should be cancelled from the claims to clarify that the applicant is invoking 112, 6th paragraph.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. With respect to claim 16, the claimed invention is directed to non-statutory subject matter. Without specifying that it is a non-transitory computer product the claimed invention could possibly implemented as data incorporated on a digital signal.

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However, signals are not patentable subject matter. When a claim covers both statutory and non-statutory embodiments it is proper to reject as including nonstatutory subject matter.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Boppart et al. (WO 98/38907-cited by applicant).

With respect to claims 1-2, Boppart et al. discloses an apparatus for determining a property of a fluid which flows through a biological tubular structure, the apparatus operable for performing an optical detection step for determining a position of the biological tubular structure, performing an optical spectroscopic step for determining of the property of the fluid in a detection volume, the location of the detection volume being determined by the position, whereby a first numerical aperture is used for performing the optical detection step and a second numerical aperture is used for performing the optical spectroscopic step, and whereby the first numerical aperture is smaller than the second numerical aperture, whereby an objective having a variable numerical aperture is used for performing the optical detection step and for performing

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the optical spectroscopic step (page 4, lines 4-5, page 28, line12-page 31 line 9, page49, line12- page 51 line 2) .

With respect to claims 9-10, the first numerical aperture and the second numerical aperture range from 0.1 to 0.5 and higher (page 49 lines 11-18).

With respect to claims 11-13, tracking a movement of the biological tubular structure by imaging of the biological tubular structure with the second numerical aperture, optically determining a depth of the biological tubular structure under a surface of the body using the second numerical aperture, and performing a number of imaging steps with the second numerical aperture for scanning along a direction being transversal to the surface of the body in order to determine the depth (page 7, lines 11-20, page 31 line 18- page 33 line 20, page 49 line 11- page 51 line 2).

With respect to claim 14, the fluid is blood and the biological tubular structure is a blood vessel (page 4 lines 4-5, page 38 lines 13-16, page 68 lines 1-15).

With respect to claim 15, the first numerical aperture is used for determining two dimensions of the position and the second numerical aperture is used for determining the third dimension of the position (page 28, line12-page 31 line 9, page49, line12- page 51 line 2).

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With respect to claim 16, a computer program product, in particular a digital storage medium, for controlling of optical detection means and optical spectroscopic means by the steps of controlling of the optical detection means for determining a position of a biological tubular structure through which a fluid flows, controlling of the optical spectroscopic means to determine a property of the fluid in a detection volume, a location of the detection volume being determined by the position, whereby the optical detection means is controlled to perform the position determination with a first numerical aperture and the optical spectroscopic means is controlled to perform the spectroscopic determination of the property using a second numerical aperture, whereby the first numerical aperture is smaller than the second numerical aperture (page 8 line 18- page 9 line 3, page 17 lines 6-11, page 15 line 20- page 16 line 5, page 28 line 12 - page 31 line10).

With respect to claim 17, Boppart et al. discloses an apparatus for determining a property of a fluid which flows through a biological tubular structure, the apparatus comprising optical detection means for determining a position of the biological tubular structure, optical spectroscopic means for determining a property of the fluid in a detection volume, the location of the detection volume being determined by the optical detection system, optical means for providing a first numerical aperture for the determination of the position by means of the optical detection means and for providing a second numerical aperture for the spectroscopic determination of the property by means of the optical spectroscopic means, the first numerical aperture being smaller

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than the second numerical aperture (page 4, lines 4-5, page 28, line12-page 31 line 9, page49, line12- page 51 line 2).

With respect to claim 18, Boppart et al. discloses a method of determining a property of a fluid which flows through a biological tubular structure, the method comprising performing an optical detection step for determining a position of the biological, tubular structure, performing an optical spectroscopic step for determining of the property of the fluid in a detection volume, the location of the detection volume being determined by the position, whereby a first numerical aperture is used for performing the optical detection step and a second numerical aperture is used for performing the optical spectroscopic step, and whereby the first numerical aperture is smaller than the second numerical aperture (page 4, lines 4-5, page 28, line12-page 31 line 9, page49, line12- page 51 line 2).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boppart et al. (WO 98/38907-cited by applicant).

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With respect to claims 3-8, the optical detection step is performed by means of an imaging method, Raman spectroscopy, fluorescence spectroscopy, elastic scattering spectroscopy, infrared spectroscopy, and photo-acoustic spectroscopy are used for performing the optical spectroscopic step, the reference does not particularly list all of the imaging systems mentioned above but it is clear that this is all the list of general categories of imaging systems that are appropriate, therefore, it implies by using the terms “or” , “other”, “or combination thereof” mentioned in the cited portion, that one with ordinary skills in the art can recognize other particular spectroscopy techniques that would be suitable including infrared, photo-acoustic, and elastic scattering (page 7 lines 4-10).

Conclusion

11. The prior arts made of record and not relied upon are considered pertinent to applicant's disclosure. Liu et al. (USPN 6825928) discloses a fluorescence instrument which enables the measurement of fluorescent targets at various depths below the surface of a turbid medium such as tissue by varying the size of the effective illumination/collection aperture at various depths beneath the surface of the tissue for a fluorescence layer. Prahl et al. (USPN 6014204) discloses a multiple diameter fiber optic device comprises one or more optical fibers that are used to irradiate light onto a tissue and to detect light back-scattered by the tissue wherein the diameters and/or numerical apertures of the one or more fibers are selected to provide different sampling volumes within the tissue, and are chosen to emphasize differences in light penetration

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into the tissue such that the diameter and/or numerical aperture of each fiber is related to the scattering and absorption path lengths in the tissue. Shehada et al. (USPN 6124597) discloses a Laser Induced Fluorescence Attenuation Spectroscopy (LIFAS) method and apparatus preferably include a source adapted to emit radiation that is directed at a sample volume in a sample to produce return light from the sample, such return light including modulated return light resulting from modulation by the sample, determined a characteristic of interest, such as the ischemic or hypoxic condition of biological tissue. Van Beek et al. (USPN 20060258942) discloses a spectroscopic analysis apparatus, for analyzing an object, such as the blood of a patient, and an optical tracking system for continuously tracking a point of a moving object such as blood vessel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:30-18:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TSE Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3777

/MARJAN FARDANESH/
Examiner, Art Unit 3777